

A CHOICE BETWEEN FOOD AND MEDICINE: *DENNING V. BARBOUR* AND THE STRUGGLE FOR PRESCRIPTION DRUG COVERAGE UNDER THE MEDICAID ACT

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“Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.”

United Nations, *Universal Declaration of Human Rights*¹

“One becomes sick oneself, to minister to the sick, not with any false claim to having the same fever but considering, with an attitude of sympathy, how one would want to be treated if he were the sick one.”
St. Augustine²

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1. Universal Declaration of Human Rights, G.A. Res. 217 (III) A, U.N. Doc. A/RES/217(III), at 25 (Dec. 10, 1948).

2. GARY WILLS, SAINT AUGUSTINE 73 (1999).

In the eyes of many Americans, Mississippi enjoys an infamous, even paradigmatic reputation for its history of profound inequality and injustice. In the early autumn of 2005, the disastrous Hurricane Katrina revealed to many that Mississippi's status as a symbol of inequality was not based upon history alone. As University of Pennsylvania Professor Michael Eric Dyson observes, "Hurricane Katrina's violent winds and killing waters swept into the mainstream a stark realization: the poor had been abandoned by society and its institutions, and sometimes by their well-off brothers and sisters, long before the storm."³

I. BACKGROUND

A. *The Poorest State in America*

Nowhere in America is poverty greater than in Mississippi. About 21% of the population in Mississippi lives *below* the poverty level, the highest poverty rate of any state in America.⁴ Mississippi ranks fiftieth among states in the percentage of children who are poor:⁵ nearly one in three children under the age of six in Mississippi lives in poverty,⁶ and for African-American children, this figure is closer to *one-half*.⁷ Mississippi ranks fifty-first (counting the District of Columbia) in the percentage of babies born with low birthweight, fiftieth in infant mortality, and forty-sixth in per-pupil expenditures.⁸ Every thirty-seven minutes, "[a] child is

3. MICHAEL ERICK DYSON, *COME HELL OR HIGH WATER: HURRICANE KATRINA AND THE COLOR OF DISASTER* 2 (2006).

4. *State and County QuickFacts: Mississippi*, U.S. CENSUS BUREAU, <http://quickfacts.census.gov/qfd/states/28000.html> (last visited Oct. 24, 2010); *see also* ALEMAYEHU BISHAW & JESSICA SEMEGA, U.S. Census Bureau, *Income, Earnings and Poverty Data From the 2007 American Community Survey* 21 (2008), *available at* <http://www.census.gov/prod/2008pubs/acs-09.pdf>.

5. THE ANNIE E. CASEY FOUND., 2010 KIDS COUNT DATA BOOK: STATE PROFILES OF CHILD WELL-BEING 14 (2010), *available at* <http://datacenter.kidscount.org/DataBook/2010/OnlineBooks/2010DataBook.pdf>; William O'Hare & Mark Mather, *Child Poverty is Highest in Rural Counties in U.S.*, POPULATION REFERENCE BUREAU (Jan. 2008), www.prb.org/articles/2008/childpoverty.aspx (reporting on the prevalence of poverty in rural counties). "Of the 100 counties with the highest child poverty rates" in the United States, Mississippi is home to seventeen of them, the highest number in the country. *Id.*

6. *Mississippi: Demographics of Poor Children*, NAT'L CTR. FOR CHILDREN IN POVERTY, http://www.nccp.org/profiles/MS_profile_7.html (last visited Oct. 24, 2010).

7. *Id.* (reporting "43% (145,912) of black children live in poor families").

8. CHILDREN'S DEFENSE FUND, *CHILDREN IN MISSISSIPPI* 1 (2008), *available at* <http://www.childrensdefense.org/child-research-data-publications/data/state-data-repository/cits/children-in-the-states-2008-mississippi.pdf>. In fact, Mississippi ranks worst nationally in seven of ten "key indicators of child well-being." THE ANNIE E. CASEY FOUND., 2010 KIDS COUNT DATA BOOK: STATE PROFILES OF CHILD WELL-BEING 14 (2010), *available at* <http://datacenter.kidscount.org/DataBook/2010/OnlineBooks/2010DataBook.pdf>.

born into poverty” in Mississippi.⁹ And every eighteen hours, a child in Mississippi “dies before reaching his or her first birthday.”¹⁰

According to the United Health Foundation, which issues an authoritative annual report entitled, *America's Health Rankings*, Mississippi is also the least healthy state in America.¹¹ “It ranks 50th for all health determinants combined, so its overall ranking is unlikely to change significantly in the near future.”¹² Mississippi has been ranked last for the past eight straight years in this report, which examines twenty-two categories of health, including immunization coverage, premature death rates, infant mortality rates, preventable hospitalizations, and rates of cardiovascular death.¹³

Poverty is so great in Mississippi that 26% of Mississippians rely upon the Medicaid program¹⁴ as their only source of health coverage—more than one in four,¹⁵ with fully *half* of all children in Mississippi enrolled in Medicaid.¹⁶ “We have an inordinate percentage of our population that’s on Medicaid in this state,” Mississippi state representative Steve Holland

9. CHILDREN’S DEFENSE FUND, CHILDREN IN MISSISSIPPI 1 (2008), *available at* <http://www.childrensdefense.org/child-research-data-publications/data/state-data-repository/cits/children-in-the-states-2008-mississippi.pdf> (emphasizing the effect of poverty on Mississippi’s children through the use of a statistical comparison with other states). According to the Children’s Defense Fund, the amount of Mississippi’s children who are uninsured climbed from 14.9% in 2008 to 15.3% in 2009. *Id.*; CHILDREN’S DEFENSE FUND, HEALTH COVERAGE FOR ALL CHILDREN: MISSISSIPPI 1 (2009), *available at* <http://www.childrensdefense.org/child-research-data-publications/data/state-data-repository/health-coverage-state-facts/child-health-coverage-facts-mississippi.pdf>.

10. CHILDREN’S DEFENSE FUND, CHILDREN IN MISSISSIPPI 1 (2008), *available at* <http://www.childrensdefense.org/child-research-data-publications/data/state-data-repository/cits/children-in-the-states-2008-mississippi.pdf>.

11. UNITED HEALTH FOUND. ET AL., AMERICA’S HEALTH RANKINGS: A CALL TO ACTION FOR INDIVIDUALS & THEIR COMMUNITIES 7 (2009), *available at* <http://www.americashealthrankings.org/2009/report/AHR2009%20Final%20Report.pdf>.

12. *Id.*

13. *Id.* at 37 (describing disparities among different classes of Mississippi residents in health related categories).

14. For an overview of the creation, purpose, and structure of Medicaid, see HEALTH CARE FIN. ADMIN., U.S. DEP’T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2006 (2000), *available at* <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf> and THE KAISER COMM’N ON MEDICAID AND THE UNINSURED, THE HENRY J. KAISER FAMILY FOUNDATION, MEDICAID: A PRIMER 2010, *available at* <http://www.kff.org/medicaid/upload/7334-04.pdf>.

15. *Mississippi: Facts At-A-Glance*, THE HENRY J. KAISER FAMILY FOUND., <http://www.statehealthfacts.org/profileglance.jsp?rgn=26> (last visited Oct. 24, 2010) (comparing demographic and economic statistics of Mississippi with the economy of the United States as a whole).

16. AM. ACAD. OF PEDIATRICS, MISSISSIPPI MEDICAID FACTS 1 (2005), *available at* http://www.aap.org/advocacy/washing/elections/mfs_ms.pdf.

has observed.¹⁷ "It's the very foundation of health care and medical care in the State of Mississippi."¹⁸

B. *The Medicaid Program*

For tens of millions of Americans, Medicaid is the only thing standing between them and a life of pain, suffering, and premature death. Established by Congress in 1965,¹⁹ Medicaid is a public assistance program jointly funded by the federal government and state governments²⁰ to provide health coverage to qualified individuals with low income and low resources.²¹ Medicaid is state-administered, with each state setting its

17. Archive of *NOW with Bill Moyers*, Broadcast Transcript, PBS.ORG (July 16, 2004), http://www.pbs.org/now/transcript/transcript329_full.html (quoting Steve Holland on the importance Medicaid plays in the Mississippi economic and health care systems).

18. *Id.*

19. Congress enacted the Medicaid program as an amendment to the Social Security Act. 42 U.S.C. § 1396a; Pub. L. No. 89-97, 79 Stat. 286 (1965) (addressing Congress' intentions to offer aid in the form of an insurance program to the elderly). For an overview of the Medicaid program, see THE KAISER COMM'N ON MEDICAID AND THE UNINSURED, THE HENRY J. KAISER FAMILY FOUNDATION, MEDICAID: A PRIMER 1 2010, available at <http://www.kff.org/medicaid/upload/7334-04.pdf> (providing background information on the creation and expansion of Medicaid); HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2000 6 (2000), available at <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf>.

20. See *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Medicaid is a cooperative federal-state program through which the Federal Government provides financial assistance to States so that they may furnish medical care to needy individuals."); *Atkins v. Rivera*, 477 U.S. 154, 156-57 (1986) ("The Federal Government shares the costs of Medicaid with States that elect to participate in the program.").

21. The House Report accompanying the Medicaid bill observed: "These people are the most needy in the country and it is appropriate for medical care costs to be met, first, for these people." S. REP. NO. 89-404, at 1-2 (1965), reprinted in 1965 U.S.C.C.A.N. 1943, 1943-45; see, e.g., *Atkins v. Rivera*, 477 U.S. 154, 156-58 (1986) (Medicaid was "designed to provide medical assistance to persons whose income and resources are insufficient to meet the costs of necessary care and services"); *Schweiker v. Hogan*, 457 U.S. 569, 573, 591 (1982) ("They are the 'categorically needy.'"); HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 7 (2000), available at <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf> ("Medicaid provides essential medical and medically related services to the most vulnerable populations in society."); THE KAISER COMM'N ON MEDICAID AND THE UNINSURED, THE HENRY J. KAISER FAMILY FOUNDATION, MEDICAID: A PRIMER, 7 (2010), available at <http://www.kff.org/medicaid/upload/7334-04.pdf> ("By design, Medicaid covers low-income and high-need populations. Medicaid plays an especially large role in covering children and pregnant women. It also covers millions of low-income Medicare beneficiaries and individuals with disabilities and chronic conditions."). Note, however, that poverty alone is not sufficient to qualify for Medicaid. Individuals must meet strict eligibility requirements, including income and resource criteria, and immigration and residency status. See, e.g., Jane Perkins, *Medicaid: Past Successes and Future Challenges*, 12 HEALTH MATRIX 7, 10-14 (2002). Per-

own guidelines regarding eligibility and the services covered.²² The federal government then reimburses each state for a portion of the medical services provided, with rates of reimbursement that vary with each state.²³ In return, states must comply with broad mandates regarding eligibility and coverage set forth in the federal Medicaid Act and its accompanying regulations.²⁴

C. *The "PLAD" Lawsuit*

Arguing that the costs of the Medicaid program were spiraling out of control, in 2004 Governor Haley Barbour signed Mississippi House Bill 1434, eliminating from the Mississippi Medicaid program the Poverty Level Aged or Disabled (PLAD) category of coverage.²⁵ The PLAD category provided Medicaid insurance to approximately 65,000 elderly and disabled Mississippi residents with incomes between 75% and 135% of the poverty line.²⁶

The law raised a hue and cry from the tens of thousands who were slated to lose their Medicaid coverage, and attracted national attention. "Mississippi has enacted the deepest cuts any state has ever made to

kings notes, for example, that "[p]ossession of a car with an equity value of \$1,500, or less at state option, makes an applicant ineligible for Medicaid." *Id.* at 12 n.27.

22. See 42 U.S.C. § 1396a; HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2000 6-7 (2000), available at <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf> ("Each state establishes its own eligibility standards, benefits package, payment rates and program administration under broad federal guidelines."); THE KAISER COMM'N ON MEDICAID AND THE UNINSURED, MEDICAID: A PRIMER, 5 (2010), available at <http://www.kff.org/medicaid/upload/7334-04.pdf> ("[S]tates have broad authority to define eligibility, benefits, provider payment, delivery systems, and other aspects of their programs.").

23. HEALTH CARE FIN. ADMIN., U.S. DEP'T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2000 8 (2000), available at <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf> ("The federal government contributes between 50 percent and 83 percent of the payments for services provided under each state Medicaid program.").

24. See *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990) ("Although participation in the program is voluntary, participating States must comply with certain requirements imposed by the [Medicaid] Act and regulations promulgated by the Secretary of Health and Human Services."); *Atkins v. Rivera*, 477 U.S. 154, 157, 162 (1986).

25. See AARP, HEALTH AND LONG-TERM CARE: A SURVEY OF MISSISSIPPI AARP MEMBERS 1 (2004), available at http://assets.aarp.org/rgcenter/post-import/ms_ltc.pdf; see also Leighton Ku, *Mississippi's Flawed Medicaid Waiver Proposal*, CTR. ON BUDGET & POLICY PRIORITIES, 1 (Aug. 11, 2004), <http://www.cbpp.org/archiveSite/8-11-04health.pdf> (arguing that Mississippi's Medicaid waiver proposal is an inadequate substitute for PLAD beneficiaries).

26. Leighton Ku, *Mississippi's Flawed Medicaid Waiver Proposal*, CTR. ON BUDGET & POLICY PRIORITIES, 2 (Aug. 11, 2004), <http://www.cbpp.org/archiveSite/8-11-04health.pdf> (discussing H.B. 1434).

Medicaid benefits for the elderly and disabled,” Bill Moyers reported on his nationally televised program, “NOW.”²⁷ “These are truly our sickest, most vulnerable, most disabled citizens, who may rely on the state for help,” state representative Holland told Moyers.²⁸ “And yet, [the Governor] wants to do away with [the PLAD coverage]. So, starving the beast of government in this case is starving people’s lives. And that’s not right in any state in the nation.”²⁹

In September 2004, PLAD beneficiaries sued the Governor, assisted by the Mississippi Center for Justice, AARP Foundation Litigation, the National Health Law Project, the National Senior Citizens Law Center, and Mississippi attorney David Calder.³⁰ Faced with a strong lawsuit and widespread public outcry, the Governor backed down. In a consent decree issued in October 2004, the State agreed to restore coverage to all of the PLAD beneficiaries.³¹

D. *Prescription Drug Caps: Will That Be Food or Medicine for You?*

At the time of the PLAD cuts, a simple solution was proposed: raise the cigarette tax, a move that would have provided more than enough revenue to cover any shortfall in Medicaid expenditures. Given the high health care costs associated with cigarette smoking, many also viewed this as just plain good public policy: higher cigarette taxes have been shown to reduce youth smoking, maternal smoking, and tobacco-related illnesses, all of which, of course, ends up saving the state further medical expense.³² And this would not have been a case of “piling on the taxes”: Missis-

27. Archive of *NOW with Bill Moyers*, Broadcast Transcripts, PBS.ORG (July 16, 2004), http://www.pbs.org/now/transcript/transcript329_full.html; accord Leighton Ku, *Mississippi's Flawed Medicaid Waiver Proposal*, CTR. ON BUDGET & POLICY PRIORITIES 2 (Aug. 11, 2004), <http://www.cbpp.org/archiveSite/8-11-04health.pdf> (“This is the biggest cut in Medicaid eligibility for senior citizens or people with disabilities ever made by any state.”).

28. Archive of *NOW with Bill Moyers*, Broadcast Transcripts, PBS.ORG (July 16, 2004), http://www.pbs.org/now/transcript/transcript329_full.html.

29. *Id.*

30. See AARP, HEALTH AND LONG-TERM CARE: A SURVEY OF MISSISSIPPI AARP MEMBERS 1 (2004), available at http://assets.aarp.org/rgcenter/post-import/ms_ltc.pdf.

31. See *id.*; Telephone Interview with Steve Hitov, Managing Attorney: Wash., D.C. Office, Nat’l Health Law Program (Mar. 16, 2007) (on file with author).

32. There are numerous such studies. See JOHN A. TAURAS ET AL., EFFECTS OF PRICE AND ACCESS LAWS ON TEENAGE SMOKING INITIATION: A NATIONAL LONGITUDINAL ANALYSIS 17 (2001), available at http://www.uic.edu/orgs/impactteen/generalarea_PDFs/effectspriceaccesslawsteensmoking_april2001.pdf; Jeanne S. Ringel & William N. Evans, *Cigarette Taxes and Smoking During Pregnancy*, 91 AM. J. PUB. HEALTH 1851 (2001) (analyzing the effects of a cigarette tax-increase on pregnant women and concluding that a tax increase will generally lower maternal smoking during pregnancy).

issippi's cigarette tax was the third lowest in the nation, at 18 cents a pack, compared to the national average of 91.7 cents a pack.³³

Unfortunately, however, cigarette taxes are low in Mississippi for a reason. As a study released by the Center for Tobacco Control Research and Education explains:

The tobacco industry is a major political force in Mississippi through lobbying, litigation, public relations, direct campaign contributions, indirect campaign contributions, gifts and honoraria, and entertainment events. The tobacco industry has a centralized political organization that defends and promotes its political market interests in state government. Although the tobacco industry has operated in the open in some instances, it generally works quietly behind the scenes by itself, with allied organizations, and through front groups on state political campaigns.³⁴

The Governor, a former tobacco industry lobbyist, quashed the proposal. As Moyers put it, "Governor Barbour, whose clients as a lobbyist included almost all the big tobacco companies, said no . . . and no to any tax increase at all."³⁵

Forced to rescind the PLAD cuts, and having rejected the tobacco tax solution, Governor Barbour was still eager to cut Medicaid expenditures. On March 31, 2005, Barbour and the Mississippi Legislature enacted new legislation severely limiting the State's prescription drug coverage for Medicaid beneficiaries.³⁶ House Bill 1104, which went into effect on July 1, 2005,³⁷ limits beneficiaries to no more than five drugs per month, only two of which can be brand name drugs.³⁸ Under the previous policy, it-

33. Campaign for Tobacco Free Kids, "State Cigarette Excise Tax Rates and Rankings" (2007), available at www.tobaccofreekids.org/research/factsheets/pdf/0097.pdf.

34. MICHAEL S. GIVEL & STANTON A. GLANT, INST. FOR HEALTH POLICY STUDIES SCH. OF MED., UNIV. OF CAL., S.F., Political Reform and Tobacco Control Policy Making in Mississippi From 1990 to 2001, at 2 (2002), available at <http://escholarship.org/uc/item/12x7g2h9>.

35. Archive of *NOW with Bill Moyers*, Broadcast Transcripts, PBS.ORG (July 16, 2004), http://www.pbs.org/now/transcript/transcript329_full.html. In 2009, Governor Barbour finally "relented in the face of slumping budget revenues and signed the state's first increase in nearly a quarter century." *Mississippi: Barbour Signs Cigarette Tax*, N.Y. TIMES, May 14, 2009, at A20, available at 2009 WLNR 9159115. The tax increased from 18 cents to 68 cents a pack, yielding an estimated revenue of \$113 million for the year. *Id.*

36. Complaint at ¶27, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

37. *Id.* at ¶28.

38. 2005 Miss. Laws 470 (codified as amended at MISS. CODE ANN. § 43-13-117(9)(a) (West Supp. 2009)). The Mississippi law provides:

The division shall allow for a combination of prescriptions for single source and innovator multiple source drugs and generic drugs to meet the needs of the beneficiaries,

self extremely problematic for the chronically ill, Medicaid recipients could get up to seven drugs, with no brand name restrictions.³⁹

By definition, this law targets the poorest and most severely ill Mississippians, namely those Medicaid beneficiaries so ill that they require more than five drugs per month, or more than two brand name drugs. And these are known as “hard limits,” or “hard caps,” because the law permits no exceptions for severe hardship or even life-threatening circumstances.⁴⁰

For thousands of poor and critically ill Mississippians, the law is a guarantee of severe financial and physical suffering, and a potential death sentence. Thousands of chronically ill beneficiaries in Mississippi require far more than five drugs, or two brand name drugs, to treat their conditions and to stay alive. Indeed, beneficiaries living with illnesses ranging from congestive heart failure to renal failure, HIV to diabetes, often require five or more drugs—and two or more brand name drugs—just to treat those illnesses.⁴¹ Typically, these beneficiaries live with multiple diagnoses, and thus require additional drugs to treat the other illnesses. Under the Mississippi law, each month, they are forced into the impossible decision whether to treat the HIV or the cancer, the diabetes or the congestive heart failure, the pain or the cause of that pain. And every day, they must decide whether to buy food or drugs with the paltry amount of

not to exceed five (5) prescriptions per month for each noninstitutionalized Medicaid beneficiary, with not more than two (2) of those prescriptions being for single source or innovator multiple source drugs.

Id.

39. PRESCRIPTION POLICY CHOICES, PRESCRIPTION DRUG CAPS—AN INEFFECTIVE POLICY THAT HARMS PATIENTS 2 (April 2008), *available at* http://www.policychoices.org/documents/DrugCap_FastFacts.pdf (“[T]he previous policy allowed them to receive up to seven prescriptions per month . . .”).

40. *See* Grier v. Goetz, 402 F. Supp. 2d 876, 910 (M.D. Tenn. 2005) (“A hard limit is one for which there are no exceptions based on individual circumstances. In contrast, a ‘soft’ limit is one in which exceptions may be granted if after a case-by-case review an individual patient demonstrates the medical necessity for an additional drug.”).

41. *See, e.g.*, Telephone Interview with Donna Smart (Oct. 14, 2005) (on file with author) (Ms. Smart takes eighteen different prescription drugs in order to manage her health); Declaration of Brenda Davis at ¶ 9, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author) (discussing seven of the nine prescription drug medications Ms. Davis needs regularly are brand name); Declaration of Larry Davis at ¶9, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. Dec. 15, 2005) (on file with author) (illustrating Ms. Davis’ need for brand name prescription drugs as they make up four of the seven prescriptions she takes); Declaration of Andrew Curtis at ¶ 2, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author) (Mr. Curtis needs fifteen prescription drugs to maintain his health); Declaration of Dr. John Donald Bower at ¶ 7, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with author) (explaining patients with diseases such as End Stage Renal Disease and diabetes typically need a minimum of eight prescription drugs to treat their ailments).

money left over after deducting expenses from their monthly income, typically a social security check for about \$600 a month.⁴²

The case of Donna Smart⁴³ perfectly illustrates the crushing consequences of the Mississippi law. Ms. Smart was fifty-two years old when the caps were implemented, the mother of four children and grandmother of five.⁴⁴ Born and raised in Mississippi, she lived with her husband in a trailer in a grindingly poor, rural section of the state. Ms. Smart had worked throughout her life as a secretary, a waitress, and a nurse's aide. But at this point in her life, she was too disabled to work. With no money in the bank, she lived on \$599 in monthly social security payments, and she depended upon Medicaid for her health care and for her medications.⁴⁵

Ms. Smart suffered from numerous illnesses and medical conditions, many of which were quite severe, debilitating, and potentially life-threatening. To treat these illnesses and conditions, her doctors prescribed a total of eighteen medications, along with over-the-counter medications and supplements.⁴⁶ Some of the medications were to be taken "as needed," meaning that she had to fill the prescription and have the drugs handy, but not necessarily refill the prescription each month. The majority, however, required a monthly refill. It was always difficult—and painful—to live under the previous Medicaid cap of seven medications. The new hard caps made it virtually impossible.⁴⁷

Ms. Smart had endured recurrent battles with cancer. In 2003, she was diagnosed with breast cancer, and in that same year, she underwent a radical mastectomy to remove her right breast. In 2004, she was again diagnosed with breast cancer, and again underwent surgery—another radical mastectomy—to remove her left breast. Not surprisingly, Ms. Smart suffered from depression.⁴⁸

She had diabetes and suffered from wildly fluctuating blood sugar levels, for which she required insulin. Without it, her blood sugar had gone as high as 800, which is life-threatening. She also suffered from dystonia, a neurological movement disorder that causes involuntary muscle contractions and that, particularly if untreated, caused her suddenly and

42. See Section II of this Article for the struggles of *Denning v. Barbour* plaintiffs Larry and Brenda Davis, Andrea Wallace, Mary Ledbetter, Sandra Miller, and Andrew Curtis under the caps.

43. I have changed the names of Ms. Smart and the other individual plaintiffs in order to respect their privacy.

44. Telephone Interview with Donna Smart (Oct. 14, 2005) (on file with author).

45. *Id.*

46. *Id.*

47. *Id.*

48. *Id.*

unexpectedly to suffer from severe convulsions. These painful convulsions could last for minutes or even days, but with medication, they could be controlled within forty-five minutes to an hour.⁴⁹

She suffered from congestive heart failure and an artery deficiency, and in 2004, Ms. Smart had a heart attack. Following this heart attack, she underwent surgery and had a stent placed in the artery to her heart. She had high blood pressure, high cholesterol, and suffered from angina attacks that caused severe chest pain. Without proper medication, Ms. Smart was liable to suffer another heart attack or stroke at any moment.⁵⁰

Finally, Ms. Smart had painful and debilitating rheumatoid arthritis. Among other things, this caused her fingers and toes to curl up and twist, and it caused her to suffer severe pain all over her body. Tumors on her bones—both in her legs and on her pelvis—further weakened her bones and often caused her severe pain. Because of these and other conditions, she frequently required the use of a wheelchair.⁵¹

After deducting all of her expenses, including utilities, taxes, insurance, a phone, and food from her \$599 monthly income, Ms. Smart was left with little. With whatever she had left, she would buy as many of the drugs and supplements as she could. Given how expensive many of these medications are, her money didn't buy much. As a result, each month, Ms. Smart was forced to gamble on her health, choosing which of the many medications, and which of the exclusively brand name medications, she would have to miss.⁵² "I beg my doctors to give me any free samples of the other medications that I need," Ms. Smart explained.⁵³ But even when they did have free samples, they were unable to provide her with the majority of the medications she required, and the quantities were always lower than what she needed.⁵⁴

And so she suffered. In a typical month, Ms. Smart was unable to secure insulin and another drug for her diabetes; chemotherapy to treat her cancer; a blood thinner for her artery deficiency; two drugs to treat her congestive heart failure; a drug for acid reflux; one for nausea; one for high blood pressure; and another for dizziness.⁵⁵

Each of these medications was vital to her health and well-being. "Without my insulin, I'm just hoping if my blood sugar spikes again, I'll be able to get to the hospital in time before I pass out or die," Ms. Smart

49. Telephone Interview with Donna Smart (Oct. 14, 2005) (on file with author).

50. *Id.*

51. *Id.*

52. *Id.*

53. *Id.*

54. Telephone Interview with Donna Smart (Oct. 14, 2005) (on file with author).

55. *Id.*

explained.⁵⁶ “My cancer doctor told me I have to have [my cancer] drug or I’ll die. He told me I had to fill this prescription in September, which meant I had to cut off one of my other drugs.”⁵⁷ These “other drugs” included medication for her high blood pressure, medication to avoid the accumulation of plaque around the stent in her heart, and blood thinner, without which she was apt to have another stroke or heart attack because she was not getting enough blood to her brain.⁵⁸

The hardships were not only medical. With every spare dollar she had, Ms. Smart tried to buy as many medications as she could. That meant that she could not even afford gas for her stove. “I try to cook whatever food I have with the microwave oven.”⁵⁹ And there was not much.

Every day I’m looking to where my next meal will come from. I eat beans every day. I eat mayonnaise sandwiches and ketchup sandwiches. I’m grateful when my mother shares soup with me, or a friend brings me a sandwich. My body has swelled because of my illness, but I can’t afford to buy any new clothes. I ask family and friends if they might spare some used clothes that would fit me.⁶⁰

II. *DENNING V. BARBOUR*

Ms. Smart was by no means alone. In December 2005, eight plaintiffs brought a class action lawsuit in the federal courthouse in Jackson seeking an injunction against the new law on behalf of thousands of similarly situated Medicaid beneficiaries, naming Governor Barbour and the head of Mississippi Medicaid as defendants.⁶¹ The plaintiffs were represented by the same group of local and national lawyers who represented the plaintiffs in the PLAD lawsuit, together with lawyers from Housing Works in New York.

Plaintiffs’ legal theory was straightforward: the federal Medicaid Act, which the State of Mississippi is required to follow,⁶² prohibits the imposition of hard caps on prescription drugs. In 1990, Congress enacted a comprehensive statute delineating the precise limitations that a state may

56. *Id.*

57. *Id.*

58. *Id.*

59. Telephone Interview with Donna Smart (Oct. 14, 2005) (on file with author).

60. *Id.*

61. Complaint at 2–5, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005).

62. *See* *Evergreen Presbyterian Ministries, Inc. v. Hood*, 235 F.3d 908, 915 (5th Cir. 2000) (“The [Medicaid] program is voluntary; however, once a state chooses to join, it must follow the requirements set forth in the Medicaid Act and in its implementing regulations.”).

impose upon beneficiaries in its prescription drug plan.⁶³ In plain language, the law sets forth all of the “Permissible Limitations” that a state may impose,⁶⁴ with an express provision setting forth all “Other Permissible Restrictions.”⁶⁵

Included among the permissible restrictions is the right to subject individual drugs to a “prior authorization” system,⁶⁶ and to deny coverage for certain types of drugs, such as hair loss and fertility drugs.⁶⁷ The only other permissible restrictions are those “necessary to discourage waste” or to “address instances of fraud or abuse.”⁶⁸ Conspicuously absent from the list is any right to deny beneficiaries medically necessary drugs through hard caps.⁶⁹

63. See Pub. L. No. 101-508, § 4401, 104 Stat. 1388, 1388-143 to 1388-61 (codified as amended at 42 U.S.C. §§ 1396a(a)(54)(A), 1396r-8 (1990)) (mandating that states comply with the requirements for prescription drugs included in a rebate agreement) and 42 U.S.C. § 1396r-8(d) (West Supp. 2010) (setting forth those requirements); *Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 676-77 (2003) (Thomas, J., concurring) (“Title 42 U.S.C. § 1396r-8(d)(1) provides a complete list of the restrictions participating States may place on prescription drug coverage under Medicaid.”).

64. 42 U.S.C. § 1396r-8(d)(1) (West Supp. 2010). This section provides, in relevant part:

PERMISSIBLE RESTRICTIONS.—(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5). (B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—(i) the prescribed use is not for a medically accepted indication . . . ; (ii) the drug is contained in the list referred to in paragraph (2); (iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State . . . ; or (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4)

Id. § 1396r-8(d)(1).

65. *Id.* § 1396r-8(d)(6) (West Supp. 2010). This section provides, in relevant part:

OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

Id. § 1396r-8(d)(6).

66. *Id.* § 1396r-8(d)(1)(A) (West Supp. 2010).

67. See *id.* §§ 1396r-8(d)(1)(B)(i), (d)(2)(B)-(C) (West Supp. 2010) (permitting restrictions where “the prescribed use is not for a medically accepted indication”).

68. *Id.* § 1396r-8(d)(6) (West Supp. 2010). Mississippi made no claim that the law was intended to address waste, fraud, or abuse. Memorandum of Law in Support of Plaintiffs’ Motion for a Preliminary Injunction at 12, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. Filed Dec. 15, 2005) (on file with the author). It could not do so, in any event, since the law imposes across-the-board limitations without regard to circumstance. *Id.*

69. See 42 U.S.C. §§ 1396r-8(d)(1), (d)(6) (West Supp. 2010).

In addition to winning their case “on the law,” the plaintiffs were required to demonstrate irreparable harm in order to obtain an injunction. This was all too easy.

Larry Davis, 48, suffered from diabetes, rheumatoid arthritis, narcolepsy, high blood pressure, high cholesterol, acid reflux, memory loss, hearing loss, allergies, and bronchial asthma.⁷⁰ Mr. Davis also suffered from epilepsy, which caused him to seize a couple times each week.⁷¹ Two years before the lawsuit was filed, Mr. Davis suffered a stroke.⁷²

Mr. Davis lived with his wife, Brenda Davis, 48, who was developmentally disabled and likewise suffered from a host of disabling conditions, including “diabetes , . . . depression, high blood pressure, high cholesterol, and arthritis.”⁷³ Ms. Davis also had a number of “gastrointestinal problems, including acid reflux, stomach ulcers, [] a hernia,” and “a serious bladder leakage problem that cause[d] [Ms. Davis] extreme discomfort.”⁷⁴

To treat the Davis’ illnesses and conditions, doctors prescribed Mr. and Ms. Davis a total of nine and seven prescription drugs, respectively.⁷⁵ Seven of Mr. Davis’s drugs were brand name, as were four of Ms. Davis’s drugs.⁷⁶ Their total household income was \$926, which included Supplemental Security Income (SSI) payments and food stamps.⁷⁷ The new Mississippi law hit them hard.

Under the new drug caps, both of the Davises were forced to get by without many of their necessary medications, and to stretch out the medications they did secure to try to make them last longer. “I know that this practice is dangerous to my health,” Mr. Davis testified, “but the cap leaves me with no other alternative.”⁷⁸ Mr. Davis would take three-fourths, half, even a fourth of his prescribed daily dose of Albuterol, an asthma medication, and skip some days entirely. Without the normal

70. Declaration of Larry Davis at ¶ 8, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

71. *Id.* at ¶ 7.

72. *Id.* at ¶ 6.

73. Declaration of Brenda Davis at ¶ 5, Denning v. Barbour, No. 3:05-cv-00771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

74. *Id.* at ¶¶ 6–7.

75. Declaration of Brenda Davis at ¶ 2, Denning v. Barbour, Civ. Action No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author); Declaration of Larry Davis at ¶8, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with author).

76. Declaration of Brenda Davis at ¶ 9, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

77. *Id.* at ¶ 3.

78. Declaration of Larry Davis at ¶ 13, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

dose, his breathing worsened. "I now use my oxygen mask two or three times during the day; beforehand, I would only use it at night."⁷⁹ He did the same with other drugs, cutting in half his Lipitor, for high blood pressure, and skipping doses of his allergy medication two or three times a week. "As a result, my sinuses run into my throat, making me so sick that I have to throw up," Mr. Davis explained.⁸⁰

Ms. Davis similarly found it impossible to secure all seven of the drugs she needed, four of which were name brand. In fact, her doctor chose not to prescribe her a further drug to reduce the swelling caused by her high blood pressure because Medicaid would not cover the drug.⁸¹ She was fortunate to receive some free samples of a few of the drugs from her doctor. "[H]aving to request the samples is extremely embarrassing for me," Ms. Davis explained,⁸² but she had no other choice. "Our co-pays alone add up to \$30 a month, and I have been spending about \$40 a month for products to treat my bladder condition. I don't know how we will pay for our medications this month."⁸³

Out of their monthly income of \$926, the Davises paid for rent, food, a loan they took out to pay for repairs to their car, gasoline, sewer payments, and gas, electric, water, and phone bills, with virtually nothing left over each month.⁸⁴ They explained, "our expenses even exceed our income, and we can't meet all of our bills."⁸⁵ Mr. Davis told the court:

Since we are paying for some of our drugs out-of-pocket as a result of the drug cap, we are sinking deeper and deeper in debt. We probably won't be able to pay our gas bills this winter, which means that the gas company will cut off our heat. Our car broke down recently, and we can't afford to fix it. We are essentially trapped in our house . . . because we can't afford the transportation costs . . . we are going to have to start going to churches for food since we no longer have money for groceries.⁸⁶

To raise money, the Davises started having weekly yard sales to sell off whatever goods they could, but they only earned "about \$2.50 a week."⁸⁷ The toll on the Davis family was enormous:

79. *Id.*

80. *Id.*

81. Declaration of Brenda Davis at ¶ 10, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

82. *Id.* at ¶ 12.

83. *Id.*

84. *Id.* at ¶ 11.

85. *Id.*

86. Declaration of Brenda Davis at ¶ 11, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

87. *Id.* at ¶ 13.

My wife and I argue constantly about our finances. She cries all the time, and I spend so much energy on figuring out how to make my medications last longer. I'm exhausted. I just want to pull my hair out from all the stress that the Medicaid cap is causing us, and the stress only makes my depression worse. My hands and my insides shake from the stress, and I feel like there is an earthquake inside me. I recently started picking my fingernails until they bleed. I'm terrified all the time because I have no idea how we will pay for our medications.⁸⁸

Like the Davises, Andrea Wallace and her husband were doing everything they could to get the medication they desperately needed. "I have had to sell what little I have to pay for my medications," Ms. Wallace explained.⁸⁹

In September[], my husband could get only \$100 for our \$315 garden tiller. We used the money to pay for my Bactroban, Triamcinolone Topical, Vaseline, and my Triple Antibiotic. More recently, we sold our lawnmower for \$200. I filled some medications with the money but am holding on to most of it to pay for future medications. We don't have anything valuable left to sell.⁹⁰

All of the plaintiffs were forced to live without medication critical to their health and their lives. Mary Ledbetter could not afford insulin to treat her diabetes, without which she suffered dangerous blood sugar levels, dizzy spells, and poor circulation in her legs and feet, which caused discoloration.⁹¹ Sandra Miller was forced to live without several drugs, including Quianpril to treat her high blood pressure and her glaucoma medication.⁹² Her eye doctor gave her a free sample, but it wouldn't last long. "When this runs out, I don't know what I'll do," she told the court, "and I need this drug to avoid blindness."⁹³

Then there is Andrew Curtis. Mr. Curtis lives with his wife and daughter on the Gulf of Mississippi, an area devastated by Hurricane Katrina. Mr. Curtis also lives with HIV, which he had treated for fifteen years with

88. Declaration of Larry Davis at ¶ 15, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with author).

89. Declaration of Andrea Wallace at ¶ 22, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

90. *Id.*

91. Declaration of Mary Ledbetter at ¶ 7, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

92. Declaration of Sandra Miller at ¶ 8, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

93. *Id.* ¶ 7.

antiretroviral medication.⁹⁴ This medication allowed his body to resist the spread of the disease and assisted his immune system from deteriorating and causing death from opportunistic infections.⁹⁵ Mr. Curtis also suffered from a host of other illnesses and conditions, including diabetes; severe bone loss; depression; persistent oral thrush, a fungal infection of the mouth and/or throat not uncommon in people living with HIV; and severe autonomic neuropathy, or painful damage to the nerves in his legs and feet.⁹⁶ Shortly before the lawsuit was filed, Mr. Curtis's T-cell count fell below 250, and his doctor prescribed the antibiotic Bactrim to help fight off infection.⁹⁷

In all, Mr. Curtis required fifteen drugs.⁹⁸ Unfortunately, Mr. Curtis, his wife Lynn, and child Sophia lived on only \$622 in social security benefits per month, together with \$300 per month in food stamps.⁹⁹ All of their income went toward the cost of food, clothing, shelter, and other necessary bills, such as electric and water expenses.¹⁰⁰

Mr. Curtis faced a simple choice: fill the prescriptions for his HIV medications or fill the prescriptions to treat the diabetes and the severe pain caused by the HIV-related illnesses.¹⁰¹ Without medication for his severe autonomic neuropathy, for example, Mr. Curtis would be unable to walk and would require a wheelchair.¹⁰² He chose to treat the pain.

I know that HIV is a deadly disease, but since July, I have not been taking some of my HIV medications . . . because filling these prescriptions would mean that Medicaid would only cover the cost of one other generic prescription, leaving me without the other medications that I also desperately need. I understand that my health will likely deteriorate without me taking these drugs, and that I could die,

94. Declaration of Andrew Curtis at ¶ 4, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

95. *Id.*

96. *Id.* at ¶¶ 4–5, 7–9.

97. *Id.* at ¶ 4.

98. *Id.* at ¶ 2.

99. Declaration of Andrew Curtis at ¶ 11, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

100. *Id.*

101. *Id.* ¶ 3. A typical HIV “cocktail” requires a minimum of three brand name drugs. Declaration of Dr. Michael Saag at ¶¶ 12–16, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author). Under pressure from beneficiaries and advocates alike, the state agreed unofficially to exempt HIV/AIDS medications from the two brand name cap, but not from the overall five-drug cap. Telephone Interview with Steve Hitov, Managing Attorney: Wash., D.C. Office, Nat'l Health Law Program (Mar. 16, 2007) (on file with author).

102. Declaration of Andrew Curtis at ¶ 5, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

but I would be in so much pain if I didn't treat my other conditions, such as neuropathy.¹⁰³

Along with the plaintiffs' declarations, plaintiffs submitted the declarations of experts in the fields of HIV/AIDS and End Stage Renal Disease (ESRD). These declarations demonstrated the life-threatening consequences that the hard caps posed for just two of many categories of chronically ill Mississippians. Dr. Michael Saag, one of the nation's leading experts on HIV/AIDS, told the court:

This law will have devastating consequences for the health and lives of individuals living with HIV. It will cause immediate, and likely quite substantial harm for thousands of poor Mississippi residents living with HIV, and it will inevitably cause significant, unnecessary suffering and death for large numbers of these residents.¹⁰⁴

Dr. John Donald Bower, a prominent expert on ESRD in Mississippi, explained that a non-diabetic ESRD patient typically requires eight different prescribed medications, and a diabetic patient typically requires nine.¹⁰⁵ Dr. Bower cited a national study showing that "one-third [] of dialysis patients were prescribed more than 10 medications, and 10% of all hemodialysis patients were prescribed more than fifteen [] medications."¹⁰⁶ "This law will have extremely damaging consequences for the health and lives of individuals living with ESRD," Bower concluded.¹⁰⁷ "It will cause great suffering and medical complications for thousands of poor Mississippi residents living with ESRD, and it will inevitably cause suffering . . . even death."¹⁰⁸

A. *The Defendants Respond*

Governor Barbour's lawyers—the Mississippi Attorney General's Office—did not dispute that the law would cause irreparable harm. Indeed, they stipulated to the facts—and thus the suffering—recounted by the

103. *Id.* at ¶ 10.

104. Declaration of Dr. Michael Saag at ¶ 15, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

105. Declaration of Dr. John Donald Bower at ¶ 7, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with author).

106. *Id.*

107. *Id.* at ¶ 9. Patients with ESRD often suffer from additional illnesses ranging from heart disease to neurological diseases and oftentimes depression. *Id.* at ¶ 11. Many of those additional illnesses require medications and would put many patients over the five-drug Medicaid cap limit. *Id.*

108. *Id.*

plaintiffs.¹⁰⁹ Instead, they argued that the Medicaid Act did not expressly prohibit the hard caps.¹¹⁰ Although Congress expressly spelled out the “permissible restrictions” that a state can adopt with regard to prescription drugs, they contended, Congress did not expressly *prohibit* other restrictions, such as hard caps, so the caps were lawful.¹¹¹ And even though Congress did not include hard caps in the carefully crafted list of “Other permissible restrictions,” the state was free to add restrictions as it saw fit:

1396r-8(d) does not explicitly say that the restrictions are an exclusive list. For example, 1396r-8(d)(1) is entitled “Permissible Restrictions.” We know that the restrictions in (d)(1) are *not* an exclusive list because a mere five sections later the statute contains (d)(5) entitled “Other Permissible Restrictions.” Congress did not use exclusive language like “only” or “unless” in 1396r-8(d)(1) or (d)(5) to indicate that the two sections comprise an exclusive list.¹¹²

A simple analogy, however, demonstrates the illogic of this argument. Say, for example, that Congress enacts a law expressly delineating “permissible colors” that a State may use, including blue, green, and purple. “Other permissible colors” include red and yellow, in limited circumstances. Could one fairly argue that orange is also a “permissible color,” since Congress did not expressly *prohibit* orange? Of course not. Such an interpretation would render meaningless the qualifying term “permissible,” transmogrifying it into the word “suggested.” Of equal importance, the defendants’ reading would defeat the very purpose of the prescription drug provisions of the Medicaid Act, which, as Congress explained, was “assuring access by Medical beneficiaries to prescription drugs where medically necessary.”¹¹³

109. Plaintiffs’ Reply Memorandum in Support of Motion for a Preliminary Injunction at 10, *Denning v. Barbour*, No. 3:05-cv-771, 2006 WL 504032 (S.D. Miss. filed Jan. 20, 2006).

110. Defendants’ Memorandum of Law in Further Opposition to Plaintiffs’ Motion for a Preliminary Injunction at 3, 8, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Jan. 25, 2006) (on file with the author).

111. *Id.* at 8.

112. *Id.* (emphasis in original).

113. See H.R. REP. NO. 101-881 pt. 1, at 96 (Oct. 16, 1990), *reprinted in* 1990 U.S.C.C.A.N. 2017, 2110. Contemporaneous legislative history confirms Congress’ intent to ensure that beneficiaries receive the prescription drugs their physicians deem medically necessary:

However, the Committee does not intend that States establish or implement prior authorization controls that have the effect of preventing competent physicians from prescribing in accordance with their medical judgment. This would defeat the intent of the Committee bill in prohibiting States from excluding coverage of prescription drugs of manufacturers with agreements—i.e., assuring access by Medicaid beneficiaries to prescription drugs where medically necessary.

But other states had hard caps, the defendants argued, and those caps had never been declared illegal by the courts.¹¹⁴ Of course, they had never been ruled *lawful* either, since no court had yet addressed this issue. The closest case, *Grier v. Goetz*, upon which Defendants relied in *Denning*, actually supported Plaintiffs' argument.¹¹⁵ In *Grier*, the court addressed the legality of Tennessee's proposal to modify a consent decree to allow a "hard" limit of five prescriptions per month.¹¹⁶ Notably, the court did not examine whether the hard cap violated § 1396r-8; that section of the Medicaid Act was not at issue in *Grier*, since it had been waived by the Secretary of Health and Human Services.¹¹⁷ Instead, plaintiffs in *Grier* challenged the proposed caps under a Medicaid statute and regulations enacted before Congress specifically delineated the permissible restrictions that a state may impose upon Medicaid beneficiaries.¹¹⁸ In addition, unlike Mississippi, Tennessee had adopted a "shortlist" of 188 drugs, "essential, life-sustaining medications for chronic illnesses," that would not count towards the drug limits.¹¹⁹ Finally, and most importantly, Tennessee represented to the court that if it were granted permission to modify the prior authorization provisions of the consent decree, it would implement a "soft" benefit limit and allow prescriptions in excess of the cap with prior authorization.¹²⁰ The court ap-

Id.; see also *Pharm. Research & Mfrs. Ass'n of Am. v. Thompson*, 259 F. Supp. 2d 39, 64 (D.D.C. 2003) ("Responding to concerns that . . . restrictive drug lists were impacting beneficiaries' care, Congress in 1990 passed the Omnibus Budget Reconciliation Act of 1990 ("OBRA 90"), which curtailed use of such lists at the same time that it added the rebate provisions to the statute.").

114. Memorandum of Law in Opposition to Plaintiffs' Motion for a Preliminary Injunction at 23, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Jan. 4, 2006) (on file with the author) ("[N]o court has ever found Section 1396r-8(d) to prohibit monthly limits or to require states to cover every medically necessary prescription for every beneficiary").

115. *Grier v. Goetz*, 402 F. Supp. 2d 876 (M.D. Tenn. 2005).

116. See *id.* at 910.

117. See *id.* at 888 ("CMS has waived compliance with some sections of the Social Security Act to permit Tennessee to implement its reforms.").

118. Specifically, plaintiffs challenged the caps under 42 U.S.C. § 1396a(a)(19) (state plan must "provide such safeguards as may be necessary to assure that eligibility for care and services under the plan will be determined, and such care and services will be provided, in a manner consistent with simplicity of administration and the best interests of the recipients") and 42 C.F.R. § 440.230 (providing, *inter alia*: "Each service must be sufficient in amount, duration, and scope to reasonably achieve its purpose."). See *Grier*, 402 F. Supp. 2d at 888.

119. *Grier*, 402 F. Supp. 2d at 909, 913.

120. See *id.* at 910. "While the State has proposed a 'hard' limit, Dr. Hickey testified that if the State is able to implement 'effective' prior authorization, it will move to implementing 'soft' limits. . . . Similarly, the State's counsel assured the Court that if the Court granted the State's proposed modifications relating to prior authorization, the State would implement 'soft' limits." *Id.*

proved Tennessee's proposal upon the representation that Tennessee would implement a "soft" cap:

Although the "hard" limit, along with the shortlist, skirts the boundaries of 42 U.S.C. § 1396a(a)(19) and 42 C.F.R. § 440.230, the "soft" limit appropriately balances the State's utilization control goals with the "best interests of the recipients." . . . A "soft" limit is more appropriate to controlling costs by targeting the population that is having the greatest fiscal impact, rather than imposing an inflexible limit on the entire TennCare population. To that end, the Court expects that the State will submit with its proposed revisions to the 2003 Consent Decree, evidence that it has sought approval from CMS to implement a "soft" five-prescription-per-month limit.¹²¹

In February 2006, moreover, a Florida federal court examined the analogous question whether a state could remove a particular drug from coverage in a manner not expressly permitted under the Medicaid Act.¹²² The court concluded that a state is not free to add such a restriction: "The statutory scheme is carefully constructed in such a way to precisely circumscribe the only methods by which a state may remove a Medicaid-eligible drug from coverage and prevent it from either arbitrarily removing a drug or adopting its own ad hoc procedure for removing a drug from coverage."¹²³

Quite simply, Congress elected to spell out the precise restrictions that a state may impose, rather than to permit states to adopt their own ad hoc restrictions. If Congress had intended to permit states to impose hard caps on prescription drugs, it would have included this extreme limitation on coverage as a permissible restriction. It did not.¹²⁴

Finally, the defendants argued that after many disabled and elderly beneficiaries moved to Medicare drug coverage in January 2006, "only 1 percent" of beneficiaries would require more than five drugs each month,¹²⁵ and "[o]ne percent is a very good figure."¹²⁶ By the defend-

121. *Id.* at 914.

122. *Edmonds v. Levine*, 417 F. Supp. 2d 1323 (S.D. Fla. 2006).

123. *Id.* at 1330–31.

124. *See Pharm. Research and Mfrs. of Am. v. Walsh*, 538 U.S. 644, 677 (2003) (Thomas, J., concurring). "This fine-tuning of a State's ability to restrict drug coverage beyond prior authorization stands in stark contrast to the broad authority granted to States to impose prior authorization. Indeed, these provisions [including those in (d)(6)] confirm that when Congress meant to impose limitations on state authority in this area it did so explicitly."

125. Transcript of Hearing at 68, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. argued Jan. 6, 2006) (on file with the author).

126. *Id.* at 61.

ants' own count, this "very good figure" represented 5,557 indigent Mississippians who would be denied critical medications.¹²⁷

The defendants were not arguing that these beneficiaries were ineligible for coverage, or that they did not have a powerful medical need for the drugs. In fact, they admitted in court that the law would deny beneficiaries medically necessary drugs, even in life-threatening circumstances.¹²⁸ Rather, they urged a legal ruling that, under the Medicaid Act, states may deny *eligible and needy* beneficiaries coverage provided that the majority receive their drugs. In other words, a certain percentage can be simply written off. The implications of this argument are staggering: thousands of indigent and critically ill citizens deemed eligible for Medicaid coverage would not be able to treat their illnesses so long as most others could, even if they would die—or like Ms. Miller, potentially go blind—¹²⁹without treatment.

"What percentage of the population is an acceptable level to sentence to death for the crime of being sick?" asked Steve Hitov of the National Health Law Program, counsel for the plaintiffs in *Denning v. Barbour*.¹³⁰ "Even if the figure is .5 percent, that means we are saying it's okay if we let one out of every 200 persons suffer or die because we want to save money, or because we don't want to raise taxes. . . ." ¹³¹

In no other setting could such a legal argument be made. Imagine an HMO arguing the right to deny thousands of its qualified customers critical medical coverage provided that the majority received coverage? Sadly, governmental bodies in the United States commonly advance this outrageous argument when faced with claims by poor citizens wrongfully denied critical benefits. Arguing that mere "substantial compliance" is required, they contend that a certain percentage—typically thousands or even tens of thousands—of citizens can be denied subsistence benefits, from Food Stamps to medical assistance, provided that the majority is

127. *Id.*; Plaintiffs' Reply Memorandum in Support of Motion for a Preliminary Injunction at 16, *Denning v. Barbour*, No. 3:05-cv-771, 2006 WL 504032 (S.D. Miss. filed Jan. 20, 2006).

128. Transcript of Hearing at 70, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. argued Jan. 6, 2006) ("The Court: Is there any exception if the denial of such drug would result in a life threatening circumstance? [Counsel for Defendants]: We do not have that, Your Honor.").

129. Declaration of Sandra Miller at ¶ 7, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author) (describing how her glaucoma medication, Trusopt, prevents her from going blind).

130. Telephone Interview with Steve Hitov, Managing Attorney: Wash., D.C. Office, Nat'l Health Law Program, (Mar. 16, 2007). Mr. Hitov noted that his comments reflect his personal opinion, rather than that of the National Health Law Program.

131. *Id.*

served.¹³² No court has ever ruled, however, that mere substantial compliance is required in the context of prescription drugs.

B. *They Can Always Buy the Drugs Themselves*

Governor Barbour had an answer to the plaintiffs' predicament. When asked about the lawsuit, Governor Barbour suggested that "many patients can receive discounts from pharmaceutical companies."¹³³ Barbour's lawyers made a similar suggestion in court, telling the judge that beneficiaries "can always pay for whatever drug is left out-of-pocket."¹³⁴ It appeared that the Governor had not read plaintiffs' papers, summarized above. Those were only some of the stories.

John Williams, 42, lived with ESRD, type 2 diabetes, and hypertension.¹³⁵ All of his medications were critical, but he wasn't getting them all. Mr. Williams was fearful that he might become ill and require an antibiotic that he could not afford.¹³⁶ He seemed to fall ill every winter. So, against his doctor's advice, he was filling only four prescriptions a month to save a slot under Medicaid for antibiotics.¹³⁷ Specifically, he was filling only one of his prescriptions for ESRD, despite the fact that failure to take both drugs can lead to permanent skeletal damage.¹³⁸

Robert Parker, 52, was hospitalized with a bacterial infection that caused him to lose 35 pounds shortly before the lawsuit was filed, leaving him at a weight of merely 112 pounds (he is 5 feet 9 inches tall).¹³⁹ Because of the hard caps, upon discharge, Mr. Parker was forced to pay \$108 out of his extremely limited monthly income of \$575 per month for an antibiotic. As a result, he was unable to purchase the food he required

132. See Armen H. Merjian, *Substantial Compliance Permits Substantial Suffering: Debunking the Myth of a Principled "Split" in the Circuits over Mandatory Timeliness Requirements in Federal Benefits Law*, 11 B.U. PUB. INT. L.J. 191-214 (2002).

133. Emily Wagster Pettus, *Health Advocates Decry Mississippi Medicaid Drug Limits*, ASSOCIATED PRESS, Nov. 29, 2005, available at 11/29/05 APALERTMS 23:33:06.

134. Transcript of Hearing at 68, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. argued Jan. 6, 2006).

135. Declaration of John Williams at ¶ 3, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

136. *Id.* at ¶ 6.

137. *Id.*

138. Declaration of Dr. John Donald Bower at ¶ 13, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with author); Declaration of John Williams at ¶ 6, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author) (describing how one Medicaid recipient is forced to limit the number of medicine prescriptions he gets filled per month, due to Mississippi's drug cap).

139. Declaration of Robert Parker at ¶ 6, Denning v. Barbour, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author)

to regain the weight he lost in the hospital, languishing in a dangerously emaciated state.¹⁴⁰

The Governor was not completely off base: the plaintiffs might be able to buy at least some of their medications . . . provided they didn't eat. "Mississippi requires that people be poor, very poor, just in order to qualify for Medicaid," Hitov explained.¹⁴¹ "Thus, by definition, you don't have disposable income. You cannot have disposable income to be eligible for Medicaid."¹⁴²

Unfortunately, many drugs are so expensive that even starvation would not yield sufficient savings. As Dr. Saag explained to the court:

[T]he average cost of a 30-day supply of a common three-drug combination used to treat someone with HIV infection is \$1,000–\$1,500, and could be as high as \$3,500–\$4,000, depending on the particular drugs. Even the cost of just one of these drugs can meet or exceed the total available monthly income, to say nothing of disposable income, of the typical Medicaid recipient who is living in poverty.¹⁴³

C. Controlling Costs

All of this was done in the name of controlling Medicaid costs. According to the State, the cuts would result in a savings of \$5.3 million a month.¹⁴⁴ This figure is, however, highly misleading. As noted, Medicaid is a joint state and federal program in which the federal government reimburses each state for a portion of the medical services provided.¹⁴⁵ Mississippi happens to receive the most generous reimbursement rate in the nation, at 77%.¹⁴⁶ In other words, for every dollar that Mississippi spends on Medicaid, the federal government reimburses Mississippi sev-

140. *Id.* at ¶¶ 6–8.

141. Telephone Interview with Steve Hitov, Managing Attorney: Wash., D.C. Office, Nat'l Health Program (Mar. 16, 2007).

142. *Id.*

143. Declaration of Dr. Michael Saag at ¶ 16, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

144. E-mail from David Miller, Staff Attorney, Miss. Ctr. for Justice, to Armen H. Merjian, Attorney, (Mar. 21, 2006, 06:58 CST) (on file with the author) (confirming that the State projected a savings in the coming year of \$64 million, or \$5.3 million per month).

145. See *Wilder v. Va. Hosp. Ass'n*, 496 U.S. 498, 502 (1990); *Atkins v. Rivera*, 477 U.S. 154, 156–57 (1986); HEALTH CARE FIN. ADMIN., DEPT OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2000 8 (2000), available at <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf> (explaining that the federal government typically contributes between 50–83% of the Medicaid expenses incurred for services provided to beneficiaries).

146. AM. ACAD. OF PEDIATRICS, NAT'L ASSOC. OF CHILDREN'S HOSP., MISSISSIPPI MEDICAID FACTS 2 (2005), available at http://www.aap.org/advocacy/washing/elections/mfs_ms.pdf (providing a snapshot the state of Medicaid in Mississippi); HEALTH CARE FIN.

enty-seven cents. Overall, then, Medicaid services are actually a source of *revenue* for the state of Mississippi, bringing seventy-seven federal dollars into the State for every twenty-three dollars the State spends on Medicaid.¹⁴⁷

Given the 77% federal reimbursement, the hard caps at issue in *Denning* would actually yield a savings to the State of Mississippi of a mere \$1.22 million dollars a month.¹⁴⁸ Thousands of poor and severely ill Mississippians suffered each day to enable the state to save a little over one million dollars a month. Meanwhile, for a few pennies on the ill-advisedly low cigarette tax—a move that Mississippi should have made a matter of public health and public policy—the State could have ensured that none of these beneficiaries went without their life-sustaining medication.¹⁴⁹

So great is the inequality in this country, moreover, that *thousands* of the poorest and sickest citizens in this country must suffer, and many must surely die prematurely, for an amount, annually, that represents but .026% of the net worth of just *one* Mississippi native, Oprah Winfrey,

ADMIN., DEP'T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2000 36 (2000).

147. See LEIGHTON KU, CTR. ON BUDGET & POLICY PRIORITIES, Mississippi's Flawed Medicaid Waiver Proposal 2 (Aug. 11, 2004), *available at* <http://www.cbpp.org/archiveSite/8-11-04health.pdf> (commenting on the proposed PLAD cuts and observing that because "Mississippi has the highest federal Medicaid matching rate in the nation—it earns more than \$3 in federal matching funds for every dollar the state spends on Medicaid—eliminating Medicaid coverage for tens of thousands of Mississippians will cost the state tens of millions of dollars in matching federal funds.").

148. This represents Mississippi's 23% share of \$5.3 million a month.

149. See MICHAEL S. GIVEL & STANTON A. GLANTZ, INST. FOR HEALTH POLICY STUDIES SCH. OF MED., UNIV. OF CAL., S.F., POLITICAL REFORM AND TOBACCO CONTROL POLICY MAKING IN MISSISSIPPI FROM 1990 TO 2001, at 3 (2002), *available at* <http://escholarship.org/uc/item/12x7g2h9> (attributing the power and political force the tobacco industry wields to political contributions and extensive lobbying efforts); ERIC LINDBLOM, CAMPAIGN FOR TOBACCO-FREE KIDS, STATE CIGARETTE EXCISE TAX RATES & RANKINGS (2010), *available at* www.tobaccofreekids.org/research/factsheets/pdf/0097.pdf (listing state-imposed cigarette tax rates currently in effect); Jeanne S. Ringel & William N. Evans, *Cigarette Taxes and Smoking During Pregnancy*, 91 AM. J. PUB. HEALTH 1851 (2001) (analyzing the effects of a cigarette tax increase on pregnant women and concluding that a tax-hike will generally lower maternal smoking during pregnancy); JOHN A. TAURAS ET AL., EFFECTS OF PRICE AND ACCESS LAWS ON TEENAGE SMOKING INITIATION: A NATIONAL LONGITUDINAL ANALYSIS 17 (2001), *available at* http://www.uic.edu/orgs/impactteen/general_area_PDFs/effectspriceaccesslawsteensmoking_april2001.pdf (discussing economic incentives to decrease smoking among American youth); Archive of *NOW with Bill Moyers* Broadcast Transcripts, PBS.ORG (July 16, 2004), http://www.pbs.org/now/transcript/transcript329_full.html (examining the motivation for Governor Barbour's resistance to an increase in cigarette taxes); *Mississippi: Barbour Signs Cigarette Tax*, N.Y. TIMES, May 14, 2009, at A20, *available at* 2009 WLNR 9159115.

whose reported net worth totals \$2.4 billion.¹⁵⁰ Indeed, simple bank interest of 5% on Ms. Winfrey's wealth would alone suffice to provide all of the additional medications that the thousands of *Denning* beneficiaries require and still leave Ms. Winfrey with about \$56 million a year on which to scrape by, without even touching the \$2.4 billion in the bank.¹⁵¹

And even the \$1.22 million monthly figure is misleading. Without proper medication, elderly, disabled, and chronically ill beneficiaries are far more likely to require emergency-room treatment, hospitalization, and institutionalization, all of which are extremely expensive. Providing essential drugs to these individuals actually helps to decrease utilization of these costly methods of treatment, and thus reduces a state's long-term healthcare costs. Numerous studies bear out this fact.¹⁵² As Stephen B. Soumerai, a leading expert in the field, explains:

[W]ell-controlled studies demonstrate that arbitrary limits on the number of Medicaid prescriptions reimbursed for chronically ill elderly and disabled people resulted in a 35 percent reduction in the use of clinically essential drugs (e.g. insulin), particularly among those with mental health problems or chronic pain; increased exacerbation of chronic illness; and a 200 percent increase in the use of more expensive services (e.g. nursing homes and emergency mental health services) that exceeded the cost of drugs.¹⁵³

150. See *The World's Billionaires: #400 Oprah Winfrey*, FORBES.COM (March 10, 2010, 6:00 PM), http://www.forbes.com/lists/2010/10/billionaires-2010_Oprah-Winfrey_OOZT.html.

151. If Ms. Winfrey chose to give out \$10,000 each day to an indigent Mississippian, working 365 days a year, it would take her 657 years to exhaust her wealth, not counting the appreciation on that wealth.

152. See, e.g., John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, 354 NEW ENG. J. MED. 2349, 2356 (2006), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMs054436> ("Overall, subjects whose benefits were capped had higher rates of non-elective hospitalizations, visits to the emergency department, and death. In addition, subjects whose benefits were capped had lower pharmacy costs but higher hospital and emergency department costs, with no significant difference in total medical costs between the two groups."); see STEPHEN B. SOUMERAI, AARP PUB. POLICY INST., *BENEFITS AND RISKS OF INCREASING RESTRICTIONS ON ACCESS TO COSTLY DRUGS IN MEDICAID V* (2004), available at http://assets.aarp.org/rgcenter/health/2004_04_access.pdf; Stephen B. Soumerai et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 NEW ENG. J. MED. 1072 (1991), available at <http://www.nejm.org/doi/pdf/10.1056/NEJM199110103251505>.

153. STEPHEN B. SOUMERAI, AARP PUB. POLICY INST., *BENEFITS AND RISKS OF INCREASING RESTRICTIONS ON ACCESS TO COSTLY DRUGS IN MEDICAID 2* (2004), available at http://assets.aarp.org/rgcenter/health/2004_04_access.pdf. Discussing an early, influential study of hard caps in New Hampshire, another leading scholar explained:

[O]nce the limits were applied the New Hampshire Medicare patients ended up in nursing homes, hospitals, or cemeteries significantly more often than the similar New

The policy of imposing hard drug caps is thus not only deleterious to the health of thousands of indigent Medicaid beneficiaries, but pennywise and pound foolish. This is particularly true of Mississippi: for a mere \$1.22 million monthly investment in providing essential drugs to the most medically needy, the State would receive \$4.08 million a month in federal dollars, saving the State many millions of dollars in long-term medical costs.¹⁵⁴ Lifting the hard caps would actually *save* the State of Mississippi money in the long term.

D. "Friend of the Court"

In January 2006, briefing and oral argument were concluded in the case. The plaintiffs eagerly awaited the court's decision, hoping for a preliminary injunction to bring an immediate end to the hard caps. In March 2006, however, they learned that the court, *sua sponte*, had decided to ask the United States Department of Health and Human Services (DHS), which oversees the Medicaid program, to file an amicus curiae brief setting forth the federal government's position on the hard caps.¹⁵⁵ This was potentially ominous news: courts generally defer to agency interpreta-

Jersey Medicaid patients, who retained full drug coverage. . . . When the cap policy was abandoned, the survival curves for the two states became parallel again: the rate of institutionalization, hospitalization, or death in New Hampshire Medicaid patients once again was the same as in the comparable patients in the New Jersey Medicaid, but with one important difference. Nearly all those extra patients in New Hampshire who were put into nursing homes because of the cap policy stayed there, incurring the human and economic toll of institutionalized life every year until they died.

JERRY AVORN, *POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS* 195 (2004).

154. See AM. ACAD. OF PEDIATRICS, NAT'L ASSOC. OF CHILDREN'S HOSP., MISSISSIPPI MEDICAID FACTS 2 (2005), *available at* http://www.aap.org/advocacy/washing/elections/mfs_ms.pdf; HEALTH CARE FIN. ADMIN., DEP'T OF HEALTH AND HUMAN SERVS., A PROFILE OF MEDICAID: CHARTBOOK 2000 36 (2000), *available at* <http://www.cms.gov/TheChartSeries/downloads/2Tchartbk.pdf> (indicating that Mississippi receives the highest Federal Medical Assistance Percentage Matching Rate of 76.80%); LEIGHTON KU, CTR. ON BUDGET & POLICY PRIORITIES, Mississippi's Flawed Medicaid Waiver Proposal, 2 (Aug. 11, 2004), <http://www.cbpp.org/archiveSite/8-11-04health.pdf> (explaining that by eliminating "Medicaid coverage for tens of thousands of Mississippians will cost the state tens of millions of dollars in matching federal funds"); Shaila Dewan, *In Mississippi, Soaring Costs Force Deep Medicaid Cuts*, N.Y. TIMES, July 2, 2005, at A8, *available at* 2005 WLNR 10415600 (describing the nature of the cap on prescription drugs in Mississippi); E-mail from David Miller, Staff Attorney, Miss. Ctr. for Justice, to Armen H. Merjian, Attorney, (Mar. 21, 2006, 06:58 CST) (on file with the author) (confirming that the state projected a savings in the coming year of \$5.3 million per month).

155. Order on Amicus Brief at 3-4, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Mar. 8, 2006) (on file with the author).

tions of the law where the relevant statute is ambiguous.¹⁵⁶ Plaintiffs observed, however, that there is nothing ambiguous about a statute that sets forth the precise limitations on drug coverage that are “permissible,” limitations that do not include hard caps on the number of drugs available.¹⁵⁷ Where a statute is clear, the interpretation of a bureaucratic agency is irrelevant.¹⁵⁸ In addition, the federal agency had already approved Mississippi’s Medicaid plan, albeit without specifically examining the drug caps.¹⁵⁹ Its position was as predictable as it was irrelevant.

Not surprisingly, in April 2006, the United States Attorney General’s Office, on behalf of DHS, argued that the statute in question “does not say anything, one way or the other, that directly and specifically addresses such monthly caps.”¹⁶⁰ The statute indeed lists the “Permissible restrictions” that a state may impose, the Attorney General’s office asserted, but it doesn’t include the words “all the,” as in “all the permissible restrictions”: “it’s just plaintiffs’ language.”¹⁶¹

In other words, when Congress explicitly listed the permissible restrictions, it really meant “some of” the permissible restrictions. Other restrictions, such as hard caps, were permissible even if not on the list of specific restrictions Congress had enumerated. To repeat the analogy, according to this argument, a specific list of “permissible colors” should not prohibit a state from choosing any other color it might select, unless Congress adds the words “all the” before “permissible colors.” Any other reading, the federal lawyers argued, would mean that “States would no longer be able to place reasonable limits on the overall extent to which they choose to cover prescription drugs.”¹⁶² Here was the federal gov-

156. *See, e.g., Good Samaritan Hosp. v. Shalala*, 508 U.S. 402, 414 (1993) (“Confronted with an ambiguous statutory provision, we generally will defer to a permissible interpretation espoused by the agency entrusted with its implementation.”).

157. Plaintiffs’ Reply Memorandum in Support of Motion for a Preliminary Injunction at 3–4, *Denning v. Barbour*, No. 3:05-cv-771, 2006 WL 504032 (S.D. Miss. filed Jan. 20, 2006).

158. *See, e.g., Chevron U.S.A., Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 842–43 (1984) (“First, always, is the question whether Congress has directly spoken to the precise question at issue. If the intent of Congress is clear, that is the end of the matter; for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”). “The judiciary is the final authority on issues of statutory construction and must reject administrative constructions which are contrary to clear congressional intent.” *Id.* at 843 n.9.

159. Telephone Interview with Steve Hitov, Managing Attorney: Wash., D.C. Office, Nat’l Health Program (Mar. 16, 2007).

160. Brief of U.S. Dep’t of Health & Human Servs. as Amicus Curiae Supporting Defendants at 6, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Apr. 6, 2006), ECF No. 30 (on file with the author).

161. *Id.* at 7.

162. *Id.* at 8.

ernment—echoing Mississippi’s position—arguing that hard caps that leave thousands of poor citizens without the drugs they require to avoid suffering, and even death, constitute “reasonable limits.”¹⁶³

III. CONCLUSION: DECISION PENDING

In the face of rising Medicaid costs, there is always a temptation to adopt a “quick fix” by capping drug expenditures, as Mississippi has done. States cannot, however, ignore the purpose of Medicaid: to provide medical assistance to individuals who are unable to bear the financial burden of necessary medical costs.¹⁶⁴ Placing a hard cap on prescription drugs, even where medically necessary—and indeed even where essential to avoid death¹⁶⁵—wholly defeats that purpose. Not surprisingly, then, hard caps are conspicuously absent from the list of “permissible restrictions” that a state may impose when providing drug coverage under the Medicaid Act.¹⁶⁶

Not only are hard caps like those in Mississippi illegal, and not only do they cause untold suffering for thousands of desperately needy individuals, but, as discussed, they reflect poor fiscal and public health policy.¹⁶⁷ By randomly capping the number of drugs available, regardless of medical need, such caps ensure increased institutionalization, emergency room

163. *Id.*

164. 42 U.S.C. § 1396-1 (2006). Congress sought to further this goal by providing prescription assistance to the neediest Americans. *Id.*; see H.R. REP. NO. 101-881 pt. 1, at 96 (Oct. 16, 1990), reprinted in 1990 U.S.C.A.N. 2017, 2110.

165. See Transcript of Hearing at 70, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. argued Jan. 6, 2006) (defendants acknowledge that no exception exists to the cap for life-saving drugs).

166. See 42 U.S.C. § 1396r-8(d)(1), (d)(2), (d)(6) (West Supp. 2010) (establishing the limitations a State may impose in its issuance of Medicaid and creating a “prior authorization” program, which allows the denial of coverage of certain drugs; however, absent from the permissible restrictions is the right to use hard caps to prevent beneficiaries from obtaining medically necessary drugs); Memorandum of Law in Support of Plaintiffs’ Motion for a Preliminary Injunction 12, *Denning v. Barbour*, No. 3:05-cv-771 (S.D. Miss. filed Dec. 15, 2005) (on file with the author).

167. See JERRY AVORN, POWERFUL MEDICINES: THE BENEFITS, RISKS, AND COSTS OF PRESCRIPTION DRUGS 195 (2004); John Hsu et al., *Unintended Consequences of Caps on Medicare Drug Benefits*, 354 NEW ENG. J. MED. 2349, 2356 (2006), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMsa054436>; STEPHEN B. SOUMERAI, AARP PUB. POLICY INST., BENEFITS AND RISKS OF INCREASING RESTRICTIONS ON ACCESS TO COSTLY DRUGS IN MEDICAID v. 2 (2004), available at http://assets.aarp.org/rgcenter/health/2004_04_access.pdf (examining the negative consequences that can arise from cost containment practices); Stephen B. Soumerai et al., *Effects of Medicaid Drug-Payment Limits on Admission to Hospitals and Nursing Homes*, 325 NEW ENG. J. MED. 1072 (1991), available at <http://www.nejm.org/doi/pdf/10.1056/NEJM199110103251505>.

utilization, and hospitalization, the costs of which counterbalance the savings realized in implementing the caps.

The refusal to raise cigarette taxes is similarly unsound, both fiscally and as a matter of public health. Although Mississippi finally raised its cigarette tax after the filing of *Denning*, it remains among the lowest rates in the nation,¹⁶⁸ and Mississippi has thus far not used the enhanced revenue to restore drug coverage for the *Denning* plaintiffs.

Reflecting on the *Denning* case, Plaintiffs' counsel Hitov observed:

This case is a stark demonstration of the fact that whatever system [of health] we have here in this country, it is not founded on the premise that there is a human right to health care. If you embrace health care as a human right, it is not subject to curtailment according to the vagaries of the economy or the people running the government. What Mississippi did with drugs is synonymous with shutting off a life-sustaining oxygen machine for a segment of the population, in the name of cost-cutting. That they can think it is permissible to do this is a reflection of the fact that they don't view health care as a human right, or even a civil right, but rather as a consumer product.¹⁶⁹

At the time of this writing, the federal district court had yet to issue an injunction or decision. Years after the enactment of House Bill 1104, thousands of poor Mississippians remained helpless to avoid the caps, still hoping for the day when they may no longer be forced to choose between food and medicine, pain medication or HIV treatment, cancer therapy or insulin. Let us hope that day arrives very soon.

168. Mississippi ranks 37th in the nation, with a tax of \$0.68 per pack, compared with the national average of \$1.45 a pack. ERIC LINDBLOM, CAMPAIGN FOR TOBACCO-FREE KIDS, STATE CIGARETTE EXCISE TAX RATES & RANKINGS (2010), available at www.tobaccofreekids.org/research/factsheets/pdf/0097.pdf.

169. Telephone Interview with Steve Hitov, Managing Attorney: Wash., D.C. Office, Nat'l Health Program (Mar. 16, 2007).

